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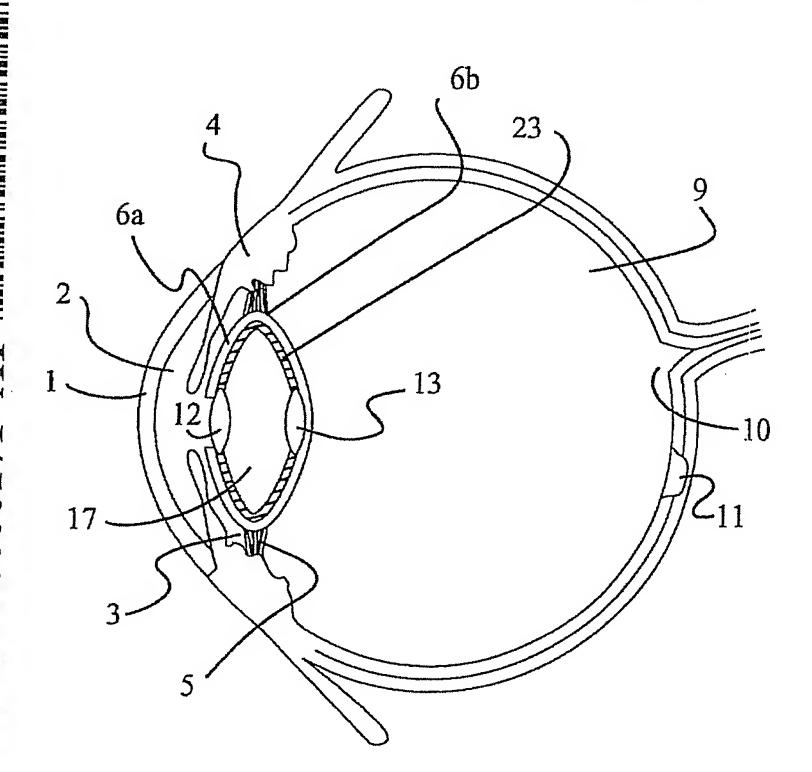
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(54) Title: ELLIPTICAL ACCOMMODATIVE INTRAOCULAR LENS



(57) Abstract: An elliptical accommodative intraocular lens assembly is provided for placement in the evacuated capsular bag of the posterior chamber of an eye after a small incision capsulorhexis, such that as the capsular bag is pulled and released by ciliary muscles, the lenses approach and withdraw from each other to provide focal accommodation.

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ELLIPTICAL ACCOMMODATIVE INTRAOCULAR LENS

FIELD OF THE INVENTION

This invention relates to intraocular lenses for implanting in the capsular bag of the posterior chamber of the eye after an anterior capsulorhexis. After implantation the lens makes use of the ciliary muscle to adjust the refractive power of the lens.

BACKGROUND OF THE INVENTION

Cataract extraction is the most common ophthalmic surgical procedure performed in the United States. Extracapsular cataract extraction involves cutting a portion of the anterior capsule (anterior capsulorhexis) followed by removal of the nucleus. Alternatively, a probe may be inserted through the anterior capsule and ultrasonically vibrated, transforming lens material into an emulsion is then irrigated and aspirated from the capsular bag (phacoemulsification). After removal of the natural lens, images no longer focus on the retina and a replacement lens must be provided for clear vision. Replacement lenses can be glasses, contact lenses or intraocular lenses. Of these, intraocular lenses give the greatest convenience and undistorted vision, however, for insertion of a lens, the size of the incision is dictated by the size of the implant rather than requirements of removing the natural lens. Replacement lenses, however, lack the ability of a natural lens to accommodatively focus on near and far objects.

When a person looks at an object, light is reflected from the object through the cornea, the aqueous humor, through the pupil and into the lens which converges the light through the vitreous body onto the retina. To clearly focus on near objects, light

rays must be bent more. To accomplish this the lens becomes more curved and thicker. Most of this change comes from pulling and relaxing the capsular bag at its equator. The equator of the bag is attached to the ciliary muscle by filaments called the zonules of Zinn which are in turn attached to the ciliary muscle. When looking at an object in the distance, the ciliary muscle relaxes and expands, thereby pulling on the zonules, flattening the capsule and lens. When looking at a near object, the ciliary muscle tenses and contracts moving the muscle slightly inward and relaxing the pull on the zonules, allowing the capsular bag to become more curved and thickened from front to back. The lens itself is composed of interlocking fibers which affect the elastic movement of the lens so that as the lens changes shape the fibers alter their curvature. As a person ages, the accommodative ability of the lens decreases which changes in the eye. Age related eye changes include thickening of the lens, an increase in the amount of insoluble protein in the lens, a migration in the points of attachment of the zonules away from the equator of the capsule, and partial liquefaction of the vitreous body.

Lenses are made from transparent material having the shape of a body of rotational symmetry, such as a sphere. The degree of curvature of the surface is inversely proportional to the radius of curvature and the focal length. Parallel light rays converge after being refracted through a convex surface and diverge after being refracted through a concave surface. Refractive power of a lens is dependent upon the refractive index of the lens material and the lens curvature. A simple lens has two sides, each with a curvature. Two lenses separated by a given distance, can be considered as one thick lens having two foci and two principal planes. The focal

length of the system is the product of their focal lengths (f_1, f_2) divided by the sum of their focal lengths minus the distance (d) between them i.e.

$$F=(f_1f_2)/(f_1=f_2-d)$$

When the space between the lenses is not a vacuum but contains a substance, the amount subtracted from the sum of the focal length is divided by the refractive index (n) of that substance.

$$F=(f_1f_2)/(f_1+f_2-d/n)$$

The refractive power of a lens system is given by the inverse of the focal length. By using two fixed lenses and varying the distance between them, a system of variable focal length can be constructed. If the curvature of one or both of the lens surfaces increases as the distance between lenses is increased, and decreases as the distance between the lenses is decreased, the change in focal length is enhanced.

Several attempts have been made to provide the eye with focal length accommodation. The most familiar of these is a bi or multi-focal lens. These are used in glasses, contacts, and intraocular lenses but have a disadvantage in that the focal accommodation is dependent upon direction of focus.

U.S. Pat. No. 4,254,509 discloses a lens which takes advantage of the ciliary muscle. However, this lens is placed in the anterior chamber of the eye. Such implants are at times accompanied by complications such as damage to the vascular iris.

U.S. Pat. No. 4,253,199 discloses a lens attached directly to the ciliary body.

The lens is in a more natural position but requires suturing to the ciliary body risking massive rupture during surgery and bleeding from the sutures.

U.S. Pat. No. 4,685,922, incorporated herein by reference, discloses a chambered lens system for which the refractive power can be changed. Such alteration is permanent, accomplished by rupture of the chambers.

U.S. Pat. No. 4,790,847 provides a single lens for in capsular bag implantation using rearwardly biased haptics which engage the capsular bag at its equator and move the lens forward and backward upon contraction and relaxation of the ciliary muscles.

U.S. Pat. No. 4,842,601, incorporated herein by reference, discloses a two section deformable lens assembly for implanting in the capsular bag. The lens allows division of refractive power and takes advantage of the action of the ciliary body and zonules on the capsular bag. This lens system is assembled after insertion.

U.S. Pat. No. 4,892,543 discloses another two lens assembly for placement in the posterior chamber, possibly in the bag where the capsular bag is not removed. This lens allows dividing the refractive power between two lenses and introduces a variable focal length in one of the lenses by compressing a flexible wall of one lens against the convex surface of the second fixed lens. This requires that the first and second lens be in substantially adjacent positions.

U.S. Pat. No. 4,932,966, incorporated herein by reference, presents an accommodative lens in which two lenses joined at their periphery enclosed a fluid filled sac, accommodation being accomplished selectively changing the fluid pressure in the sac. One lens is a rigid base lens and the other lens is membrane-like, the equatorial diameter of the lens assembly being substantially that of a dilated pupil and is supported by bladders or haptics.

BRIEF SUMMARY OF THE INVENTION

The present invention provides dual and thick lens optics, capable of accommodating focus at a range of distances in a simple unitary structure. It uses the eye capsule's natural shaping from the ciliary body to accommodate the focus.

Embodiments provide for insertion into a small incision, natural centricity, and increased focusing of the components.

DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a cross sectional view of the eye with an accommodative lens of the invention in place.

FIGURE 2 is a vertical sectional view of an eye.

FIGURE 3 is a partial sectional view showing an intraocular lens in accordance with the invention within the capsular bag when the eye is focused on a near object.

FIGURE 4 is a partial sectional view showing the intraocular lens of FIGURE 3 when the eye is focused on a distant object.

FIGURE 5 is a partial sectional view showing an alternate embodiment.

FIGURE 6 is a schematic side view of the natural lens.

FIGURE 7 is a side view of a thick lens embodiment of the lens assembly.

FIGURE 8 is a perspective sectional view of the embodiment of FIGURE 3.

FIGURES 9A and 9B are side and top views of an alternate unitary lens assembly.

FIGURE 10 is a side view of concave unitary lens.

FIGURE 10A is a side view of concave bi-element lens.

FIGURE 11 is a side view of shouldered cylindrical unitary lens.

FIGURE 12 is a side view of a cylindrical unitary lens.

FIGURES 13A and 13B are side and top views of a single shouldered unitary lens.

FIGURE 14 is a side view of a lens being inserted into a capsular bag in which the lens has been removed through a side opening.

FIGURE 15 is a side view of a cylindrical lens located in the capsular bag. FIGURE 16 is a cutaway view of a hollow unitary lens.

FIGURES 17A and 17B are perspective views of accommodative lenses with and without haptics and a helical lens connection.

FIGURE 17C is a perspective view of an accommodative lens with a third lens element.

FIGURE 17D is a perspective view of an accommodative lens with an anterior and intermediate lens elements.

FIGURES 18A and 18B are perspective and side views of cylindrical lenses having haptics.

FIGURES 19A and 19B are top views of an accommodative lens manufactured from sheet material before bending.

FIGURES 19C and 19D are side views of accommodative lenses manufactured from sheet material after bending.

FIGURES 20A, 20B and 20C are a top and two side views of a lens manufactured from sheet material.

FIGURE 21 is a plan front view of an embodiment of the accommodative lens;

FIGURE 22 is a side cross sectional view of FIGURE 21;

FIGURE 23 is a rear plan view of FIGURE 22;

FIGURE 24 shows an alternative lens element for the accommodative lens of FIGURES 21-23;

FIGURE 25 is a side cross sectional view of another embodiment of the accommodative lens of the present invention;

FIGURE 26 is a side cross sectional view of another embodiment of the accommodative lens of the present invention;

FIGURE 27 is a side cross sectional view of another embodiment of the accommodative lens of the present invention;

FIGURE 28 is a diminished sized plan front view of an alternative embodiment of the accommodative lens of the present invention;

FIGURE 29 is a side cross sectional view of still another embodiment of the accommodative lens of the present invention;

FIGURE 29A is a rear plan view of FIGURE 29;

FIGURE 30 is a side cross sectional view of a cylindrical lens of the present invention;

FIGURE 31 is a front plan view of FIGURE 30;

FIGURE 32 is an alternative embodiment of the cylindrical lens of the present invention;

FIGURE 33 is a front plan view of the FIGURE 32;

FIGURE 34 is a side cross sectional view of an embodiment of the anterior element of the accommodative lens of the present invention;

FIGURE 35 is a side cross sectional view of another embodiment of the

anterior element of the accommodative lens of the present invention;

FIGURE 36 is a side cross sectional view of another embodiment of the anterior element of the accommodative lens of the present invention;

FIGURE 37 is a cross sectional view of the lens capsule (capsular bag) of a human eye showing accommodative lens of the present invention wherein the anterior lens element is positioned against the anterior portion of the lens capsule and the posterior element is positioned against the posterior wall of the capsule;

FIGURE 38 is a cross sectional view of the lens capsule (capsular bag) of a human eye wherein accommodative lens of the present invention is positioned with the anterior lens element of the accommodative of the present invention positioned in equatorial plane region of the capsule and the posterior lens element is positioned against the posterior wall of the capsule;

FIGURE 39 is a cross sectional view of the accommodative lens of the present invention wherein the longest radial extent of the haptics is positioned midway between the anterior element and the posterior element; and

FIGURE 40 is a cross sectional view of the accommodative lens of the present invention showing two embodiments simultaneously with two embodiments of haptics.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 2 shows a cross section of the eye. As light enters the eye it passes through the cornea 1; through the aqueous humor in the anterior chamber 2; through the pupil located centric of iris 3; through the anterior wall of the capsular bag 6a; is convergently refracted by the lens 8; passes through the posterior wall of capsular bag

6b; through the vitreous humor 9 to the retina 10 at the fovea 11. The shape of the lens capsule is controlled by ciliary muscle 4 attached to the capsule by filaments called zonules 5.

The natural lens, shown in Figure 6, has a central biconvex nuclear portion 26 surrounded by a concavo-convex menisci 27a and b. Lenses which are bi convex converge light rays. Lenses which are concavo-convex have a diverging effect on light rays. Therefore the menisci of the natural lens provides a moderating effect on the converging nucleus. The anterior-posterior or polar diameter of the lens is about 5 mm. The equatorial diameter is about 9 mm.

When the natural lens 8 is removed through capsulorhexis 25, the intraocular implant shown in Figures 3 and 4 can restore focusing. The implant has an anterior lens 12 with an anterior surface 14 and a posterior lens 13 with a posterior surface 15. Extending from and connecting the equatorial perimeters of the anterior and posterior lenses is a flexible cell wall 16 forming a discoid cell 17 having an equatorial diameter substantially the same as the capsule 6. Cell 17 formed by the two lenses 12 and 13 is filled with a fluid (gas or liquid) such as air after implantation. Pressure around the equator of the cell supports the lens assembly in place.

Figure 8 shows the same lens assembly having a cell equatorial diameter of D_e , a cell polar diameter of D_p , and a polar axis $P_a P_p$. The equatorial perimeter 24 of the anterior lens 12 is substantially the size of a pupil (4-5 mm).

Although the lenses may be rigid or flexible, flexible lenses can provide greater accommodation. Anterior and posterior lenses, if rigid can be made out of a biocompatible, transparent material such as PMMA (polymethyl methacrylate), HEMA (hydroxyethyl methacrylate), polysulfones, polycarbonates, or a silicon

polymer (polydimethyl siloxanes). Materials for a soft lens would include gel forming polymers such as silica hydrogels, polysaccharides such as hyaluronic acid, or a transparent, lens-shaped sac of polyvinyl alcohol. The equatorial diameter of the anterior lens is about the size of a dilated pupil or 5 mm. Posterior and anterior lenses have a thickness of 1 to 1.5 mm. For a typical eye the anterior radius of curvature for the anterior lens is between 8 and 14 mm., and the posterior radius of curvature for the posterior lens is between 4 and 7 mm. The curvature of both faces of each lens can be altered to correct for differences in the shape of the eye (i.e. myopia). Since both lenses are converging lenses with a space between them, focal length and power is divided between them, however, if desired, the power could be in one lens. The cell wall 16 has a thickness of 0.1 mm., and can be made of a methacrylate, silicon polymer or other biocompatible, flexible material. The discoid shape is preferably an ellipsoid having a polar diameter of about 5 mm. and an equatorial diameter of 9 mm. when filled. When the ciliary muscles 4 relax and swell, the zonules 5 pull on the equator of the capsule 6, the lens assembly flattens increasing its equatorial diameter and decreasing its polar diameter thus decreasing the distance between the two lenses and altering the power of the lens assembly. If the lenses are made from a soft material, such as a lens shaped sac filled with polyvinyl alcohol, they also pull into a flatted form enhancing optical power change. To facilitate inserting the lens assembly through an incision, soft lenses could be made of a gel forming polymer and dehydrated (thus shrinking them) and the cell left unfilled until after insertion. After insertion fluids from the surrounding tissue could reconstitute the lenses and fill the cell. The cell could also be filled with a microtube or hypodermic.

Figure 5 shows an alternative form of the invention. In capsular bag 6 is a lens assembly having an anterior lens 19 with anterior curved surface 20 and a posterior lens 21 with posterior curved surface 22. Extending from and connecting the equatorial perimeters of the anterior and posterior lenses is a flexible, resilient cell wall 23 having a diameter substantially the same as lenses 19 and 21. The substantially paraboloid cell 24 thus formed may be filled with a fluid (gas or liquid) such as air. Two or more resilient haptics may be substituted for the cell wall to space the lenses and bias them against the capsular poles. The springlike action of the haptics or cell wall bias the lenses against the surface of the capsular poles supporting the lens assembly in place. As the capsular bag is pulled and released by the ciliary muscles, the lenses approach and withdraw from each other to provide focal accommodation. If a soft lens is used a support ring may be provided around the equator of the lens.

Figure 7 shows an embodiment of the invention comprising a thick lens having an anterior surface 29 and a posterior surface 30. The body of the lens 28 is substantially paraboloid. Paraboloid for the purposes of this invention includes cylindrical, hyperboloid and paraboloid. The lens is made of a resilient material to bias the anterior and posterior surfaces against the capsular poles. This springlike action supports the lens in place such that when the capsular bag is pulled and released, the anterior and posterior surfaces approach and withdraw from each other providing focal accommodation.

The lens assemblies shown in Figures 5 and 7 can be inserted through an incision substantially the width of the lens then turned or be compressed for insertion.

The unitary lens assembly of Figures 9A and 9B has anterior 100 and

posterior 102 lens surfaces and a bulged bag engaging central section 104. The lens assembly is molded in one piece from a compressible optically transparent material such as a hydrogel, silicon rubber and soft acrylics. The lens of Figure 10 has a rounded central section 106 between the anterior 108 and posterior 110 concave lens surfaces. The lens of Figure 10A has a cylinder central section 105 between the anterior 108 and posterior 110 concave lens surfaces. The lens of Figure 11 has annular ridges 112A and 112B to engage the capsular bag 6A, 6B. Figure 12 shows a lens having a cylindrical body 114, and is preferably used where the lens is inserted through a lateral capsular incision. The lens of Figures 13A and 13B has a single shoulder 116 and a body which forms a continuous curved surface 118 which includes a posterior lens surface.

Figure 14 shows a detail of the lens of Figure 12 as placed inside the capsular bag. To insert the lens, the lens 120 is compressed laterally and placed in a tube 122 similar to U.S. Patent 5,123,905, incorporated herein by reference, or by specialized forceps such as shown in U.S. Patent 4,950,289, incorporated herein by reference. The tube 122 is placed into the bag 6A, 6B and the lens 120 is forced out of the needle gently into the bag. For adequate compression, it is desirable to have a high degree of compressibility and memory in the material, or be able to dehydrate the material. Common hydrogels offer this possibility, but may lack a sufficient index of refraction necessary for proper magnification, however, means for altering the index of refraction exist such as incorporation of a solute into the hydrogel, and such hydrogels are becoming available. Alternatively a very compressible clear silicone compound may be suitable. To increase the index of refraction and to further reduce deformation of the lens surface, the surface may be provided with a thin coating of a harder

material such as quartz or PMMA, as is now done in glasses. The lens shown in Figure 15 has a cylindrical body 120 and a set of C-shaped haptics 140, 142 to provide greater positional stability.

The lens of Figure 16A and 16B is similar to that of Figure 12 except the center 124 is hollow. This allows greater compressibility for insertion.

The lens of Figures 17A and 17B has anterior 126 and posterior 128 lenses connected by a compressible helix 130. The lens of 17B is provided with bag engaging haptics 132A and 132B. The accommodative lens of Figure 17C has an intermediate lens 127 between the anterior lens 126 and the posterior lens 127. The three lenses are on a common optical axis. The haptics 132C are mounted on the helix support for the intermediate lens which will tend to position the intermediate lens in the equatorial region of the lens capsule or capsular bag. The accommodative lens of Figure 17D has no posterior lens as the accommodative lenses of Figures 17A-17C, but it has a support ring 131 at the posterior end of the compressible helix and is attached to the helix. The accommodative lens of figure 17D also has an intermediate lens 127 between the anterior lens 126 and the posterior support ring 131. The three lenses are on a common optical axis. The haptics 132C are mounted on the helix support for the intermediate lens which will tend to position the intermediate lens in the equatorial region of the lens capsule or capsular bag. The compressible helix of the accommodative lens of Figures 17A through 17D biases the anterior lens against the anterior side of the capsular bag and the biases the posterior lens or posterior ring (Fig 17D) against the posterior side of the bag. The lenses 126, 127 and 128 can be secured on their periphery to the compressible helix 130 or they can be secured on their outer periphery by lens support rings secured to the helix. The accommodate

lenses of the Figures 17A-17D can be molded in once piece or can be assembled from separate components, such as the compressible helix, lens support rings (if used) and the lenses.

The lens of Figures 18A and 18B is similar to that of Figure 12, however, it is proved with haptics 134A, 134B to stabilize the lens. Figure 18B shows an alternative haptic 150 which extends from and connects the anterior 100 and posterior 102 lenses.

Haptics may be attached to either anterior or posterior surfaces, but should be very flexible to allow for compression into a tube.

Macular degeneration requires a very strong lens. Single lenses offer an optical change of about 30 diopters, two lenses can provide up to 60 diopters. However, the greater the magnification, the smaller the field of vision. Presently, this is treated by a lens placed in front of the eye (glasses). However, by moving the posterior surface of the magnifier towards the retina, the field of vision can be increased and thus a lens assembly having two lens surfaces such as proposed here could be used for treatment of macular degeneration. Similarly, treatment of severe myopia (nearsightedness) could be treated by use of a convex surface on the posterior and/or anterior lens surfaces.

Figures 19A, B, C, D show a lens which can be made from a sheet material with some resiliency such as thin acrylic. The anterior 152 and posterior 162 lenses are Fresnal type lenses. These lenses can be provided with haptics 164A, 164B. A central ring 158 has an opening 160 to allow vision between the anterior and posterior lenses 152, 162. A bridge 154 connects the lenses with the central section. The bridge 154 is provided with creases 156 for easier bending into as from shown in Figure 19C. Figure 19B shows a similar lens having no haptics.

To provide more spring, the lens of Figure 19D has been provided with a second central ring 158. Several such sections are possible. The lens would also work if only the anterior lens were a Fresnal lens since it would move towards and away from the retina.

Figures 20A, B, and C show an alternative lens made from sheet material. The lenses 100, 102 are connected by a ring 180. When bent so that the anterior 100 and posterior lenses are located so that the optical axes are aligned, the ring 180 serves to engage the bag. Both halves of the ring may bend in the same direction as shown in Figure 20B or opposite directions as shown in Figure 20C.

The principle of this lens could be adapted into a toy for children to learn about lenses and accommodation by making a pillow with the same features of this lens. The material for this pillow is a special transparent compressible material. Handles located on the greatest circumference could be incorporated into the design. Pulling the handles outward decreases the magnification. Releasing or pushing the handles inward would increase the magnification so that it becomes an educational toy.

Referring to Figures 21-23, the accommodative lens assembly A has an anterior lens element 206A and a posterior lens element 208A. The anterior lens element 206A has a annular support element or ledge or disk 104A. The center of the ledge is open and the anterior lens 100A is positioned therein and supported on the ledge by support elements 200A. The posterior lens element 208A has a annular support element, ledge or disk 204A with a opening in the center which receives and supports the posterior lens 102A. The anterior lens element and posterior lens element can be constructed similarly such as like the anterior lens element 206A or like the

posterior lens element 208A. In other words, either lens element can have an annular ring-like ledge with the lens elements positioned in the central opening of the ring-like ledge and supported by two or more support elements or have a ledge with a central opening fully occupied by the lens to support the lens. Although illustrated with only two support elements, the lens can be supported with three, four, or more support elements as desired.

Referring to Figure 24, an alternative embodiment of the anterior lens element 206AA is illustrated which has a construction similar to that of the posterior lens element 208A shown in Figure 23. The anterior lens element 206AA of Figure 24 has an annular ledge 104B with an opening in the center which is fully occupied by the anterior lens element 100A. The haptics 202 are attached to the back side of the ledge 104B.

Referring to Figure 25, an alternative embodiment of the accommodative lens assembly B of the present invention is illustrated wherein the anterior lens element 206B and the posterior lens element 208B have a similar construction, namely they both have an annular ring-like ledges 104B and 204B and large central opening. The anterior and posterior lenses B and 200B are positioned within the center of the openings and supported by the ledges by support elements 200B and 200BB In the embodiment shown, there is illustrated alternative haptic designs 202B and 202BB.

Referring to Figure 26, another embodiment of the accommodative lens assembly C of the present invention is illustrated wherein the anterior lens element 206C is constructed similarly to the anterior lens element 206A illustrated in Figure 21 and the posterior lens element 208C is constructed similar to the posterior lens element 208A illustrated in Figure 23. In this embodiment of the invention, the

anterior portions of the haptics 202C and 202CC are secured to the support elements 200C rather than to the ledge 104C of the anterior lens element. In this figure as in many of the other figures, two embodiments of haptics are shown, 202C and 202CC, respectively, to illustrate the various haptic cross sections in side view that can be utilized in the present accommodative lens. The haptic 202CC can be reversed so that the arch of the haptic is positioned closer to the anterior lens element 206C and the horizontal section is positioned closer to the posterior lens element 208C.

Now referring to Figure 27, another side cross sectional view of another embodiment of the accommodative lens of the present invention (See also Figures 29 and 29A for another embodiment). Accommodative lens assembly D of the present invention is illustrated wherein the lens assembly has an anterior lens element 206D supporting anterior lens 100D and a posterior lens 102D but not a posterior lens element with a posterior ledge (posterior lens elements 204 as illustrated in Figures 21-23, 25 and 26 etc.). The haptics 202D are connected directly to the periphery of the posterior lens 102D and join the posterior lens to the anterior lens element 206D.

The accommodate lens arrangement of accommodative lens D can be reversed (not shown); the anterior lens 100D can secured to the haptics 202D directly as the posterior lens 102D of Figure 27 and the posterior lens 102D can be supported in an anterior lens element as shown in Figures 21, 22, etc. with the haptics 202D attached to the posterior lens element.

Now referring to Figure 29 which is a side cross sectional view of another embodiment of the accommodative lens assembly E of the present invention. In this embodiment of the present invention, there is no posterior lens element 208. There is only an anterior lens element 206E comprising ledge 104E and anterior lens 100E.

The assembly has at least one haptic 202E. The end of the haptic is attached to the upper end of the ledge 104E and the other end of the haptic circles around behind the anterior lens element connected to the bottom portion of the ledge. Preferably this assembly has two haptics which are offset 90 degrees circumferentially from the next haptic to aid positioning the assembly in the lens capsule (capsular bag). Figure 29A illustrates how haptics 202E and 202EE are connected to the outer periphery of the ledge 104E. In phantom, the posterior connection, a transparent disc 210, of the haptics 202EE and 202E is illustrated. The disc 210 is optically clear but can have an optical quality, such as an asphene surface with lillle or no optical power, or it can be a lens (See also Figure 27 for an alternative embodiment). The ends of the haptics can be molded integrally with the disc or can be attached to the disc by heat welding, adhesives, or the like. The assembly of Figure 29 has a annular ridge 212 which follows the outer periphery in the front of the ledge 104E. This ridge can aid in positioning the anterior lens element against the front wall or anterior side of the lens capsule 6A. However, the ridge is optional.

Referring to Figures 30 and 31, there is illustrated a cylindrical or tubular lens 114A having an anterior end 100F and posterior end 102F. This type of lens is very useful for telescopic effect to enlarge images. The total lens assembly 120A can have two or more haptics. In the embodiment shown in Figure 30, two different types of haptics 202F and 202FF are illustrated.

In Figure 31, assembly 120A having three haptics 202FF spaced 120 degrees apart around the outer circumference of the cylindrical lens 114A is illustrated. The haptics can be molded integrally with the lens element, or they can be secured to the lens element afterwards by heat welding or the use of medically accepted adhesives.

Referring to Figures 32 and 33, another embodiment of the cylindrical lens assembly 120B is illustrated. The lens assembly 120B comprises cylindrical lens 114B and a haptics assembly 222 comprising a sleeve 220 which fits about and is secured to the outer circumference of the cylindrical lens assembly 114B and has extending radially outwardly therefrom two or more haptics 202G. Even though most of the lens assemblies illustrated in the present invention are shown with just two haptics for ease of illustration, it is to be recognized that two or more haptics are to be employed and frequently three is an optimum number since it centers the lens assemblies of the present invention described herein within the capsular bag or lens capsule. The haptics 202G do not have to be attached to the lens 114B with a sleeve 220. The haptics can be secured to the lens by welding or use of an adhesive or they can be molded with the lens. Similarly, the haptics 202F, 202FF can be secured to the lens 114A with sleeves (not shown) in a manner similar to the way haptics 202G are secured to the lens 114B.

Referring to Figures 34, 35 and 36, the anterior and posterior ledges 104 and 204 can have other shapes rather than just flat discs. For example, Figure 34 shows in cross section a convex-concave ledge 104F with anterior lens 100F. The ledge supports lens 100F. Figure 35 shows in cross section an anterior ledge 104G having a concave anterior surface and a flat posterior surface. The ledge supports lens 100G. Figure 36 illustrates in cross section a ledge of the ring-type, such as ledge shown in Figure 21, wherein the ledge has convex surfaces on the anterior side and posterior side. In this embodiment, the anterior lens element 206H has the outer ring-type ledge 104H and a central position lens 100H which is secured to the ledge by support elements 202H. The anterior lens elements 206F, 206G, and 206H illustrate in Figures

34-36 are for illustration purposes only and are not the only shapes that can be utilized in the preparation of anterior lens elements and posterior lens elements. Posterior lens elements 208 can assume any of the shapes an anterior lens element 206 can assume.

Referring to Figures 37 and 38, capsular bags are illustrated with anterior side 6A and posterior side 6B. Accommodative lens assembly is implanted in the capsular bag by conventional means as explained herein. In Figure 37, the accommodative lens assembly provides that the anterior lens is positioned against the anterior side of the capsular bag 6A and that the posterior lens is positioned next to the posterior side of the capsular bag 6B. In Figure 38, the accommodative lens assembly is designed so that anterior lens 100II is position in the region near the equatorial plane of the capsular bag and the posterior lens 102II is positioned against the posterior side of the capsular bag 6B. Accommodative lens assembly can be designed to position the anterior lens element 206 anywhere from the next to the posterior lens element 208 all the way out to the anterior side of the capsular bag 6A.

Figures 39 and 40 illustrate accommodative lens assemblies with haptics that would position the anterior and posterior lens to a specific location within the capsular bag. For example, the accommodative lens of Figure 39 would position the anterior lens element and the posterior lens element in a manner similar to that illustrated in Figure 37. In Figure 40, the accommodative lens assembly is illustrated with two different haptics 202K and 202L. A lens assembly with haptics 202K would position the anterior lens element 206A in a manner similar to that illustrated in Figure 38. Whereas a lens assembly with haptic 202L would position the lens in such a manner that the anterior lens element 206K would be positioned on the anterior side of the capsular bag 6A and the posterior lens element would be positioned close to, if not in,

the equatorial plane of the capsular bag.

Referring to Figure 28, the plan view of the anterior lens element or posterior lens element can have a variety of shapes, including circular shapes as shown in Figures 21, 24 and 23, square shapes as shown in Figure 28, hexagon shapes and triangular shapes (not shown). It is believed that in plan view, the anterior lens elements and posterior lens elements will normally be circular-shaped. However, there may be situations where other shapes would be a benefit. In Figure 28, the ledge 104L is a square ring-type structure with a large opening where the lens 100L is positioned and secured by four support elements 200L. The posterior lens element 208 can be similar to the posterior lens element illustrated in Figures 23 or 25, or it can have a plan view similar to the anterior lens element 206L as shown in Figure 28. The support elements are shown coming off the long sides of the ledge 104L. The support elements can also extend inward from the corners to the outer periphery of the lens. The lens can be supported by two or more support elements. The ledge of Figure 28 can have a solid configuration so that the opening in the center would be fully occupied by the lens 100L as the opening in ledge 104B of Figure 24 is fully occupied by lens 100. The haptics (not shown) extending posteriorally and upwardly from the anterior lens element 206L can extend from the posterior side of the ledge 104L or from the outer periphery of 104L. In addition, the haptics as well as the lens and the support elements 200L can be molded at one time making a unitary piece or they can be secured together by adhesives or spot welding.

In the embodiments shown above, the haptics are pliable when placed in the capsular bag and move radially outward so that the haptics engage the equatorial region of the capsular bag, that is the portion of the capsular bag that has the greatest

circumference which is attached to the ciliary muscles. In one preferred embodiment of the invention, the haptics expand upwardly and outwardly to engage the inner wall of the capsular bag.

In the embodiments shown, the axis is identified by the letter O is the optical axis for the lens assembly.

What is claimed is:

1. A lens assembly comprising:

an anterior lens element, said anterior element having an anterior surface, an equatorial supporting perimeter and an optic axis;

a posterior lens element, said posterior element having a posterior surface, an equatorial support perimeter and an optic axis substantially parallel to said optic axis of said anterior lens area; and

two or more deformable haptics extending from said equatorial support perimeter of said anterior surface, to said equatorial support perimeter of said posterior surface.

- 2. The lens assembly of Claim 1 wherein the combination of the anterior lens element and the haptics are unitary.
- 3. The lens assembly of Claim 1 wherein said assembly is unitary.
- 4. The lens assembly of Claim 1 having an optical change greater than 30 diopters.
- 5. The lens assembly of Claim 1 having at least one concave lens surface.
- 6. The lens assembly of Claim 1 wherein said anterior and posterior surfaces are provided with a coating.
- 7. The lens assembly of Claim 1 wherein the assembly has three haptics.
- 8. The lens assembly of Claim 1 wherein said assembly can be dehydrated.
- 9. The lens assembly of Claim 1 having a relatively hard optic and relatively soft equatorial supporting perimeter.
- 10. The lens assembly of Claim 1 wherein said assembly is injectable.
- 11. The lens assembly of Claim 3 having at least one ledge.
- 12. The lens assembly of Claim 3 wherein said at least one ledge is annular.

13. The lens assembly of Claim 1 wherein said lens assembly is made from sheet material.

14. The lens assembly of Claim 13 wherein said assembly is foldable.

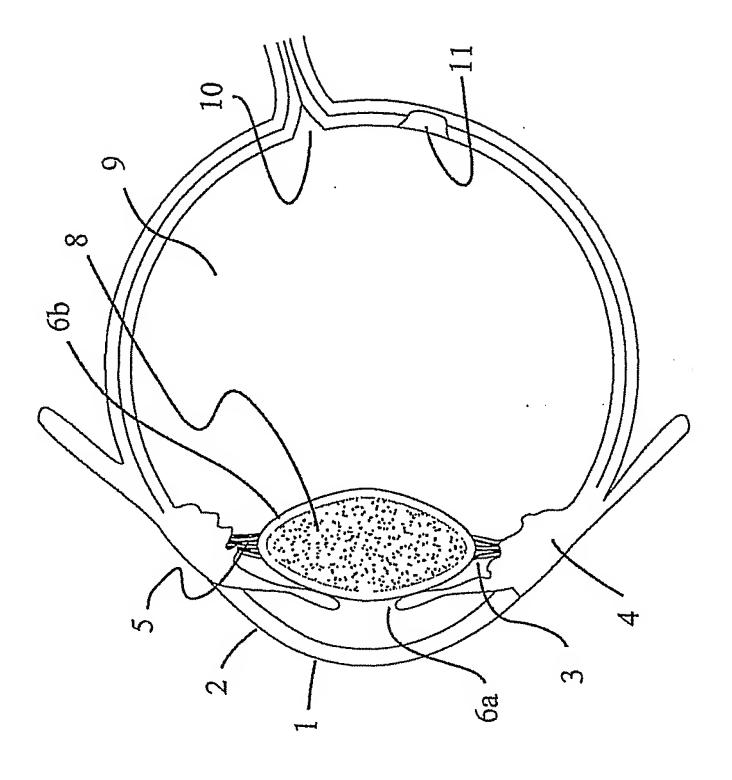
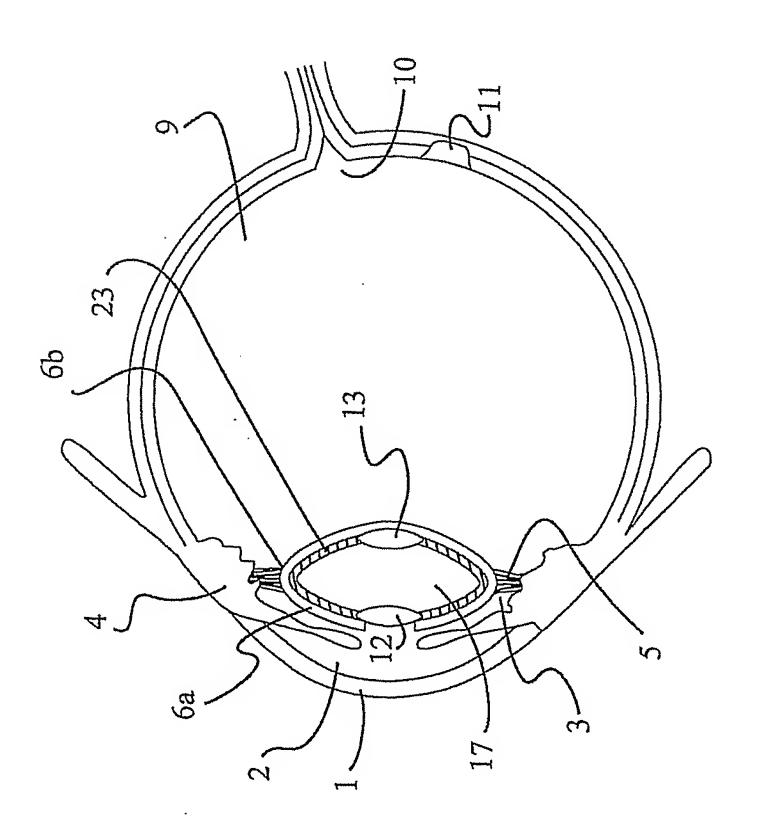
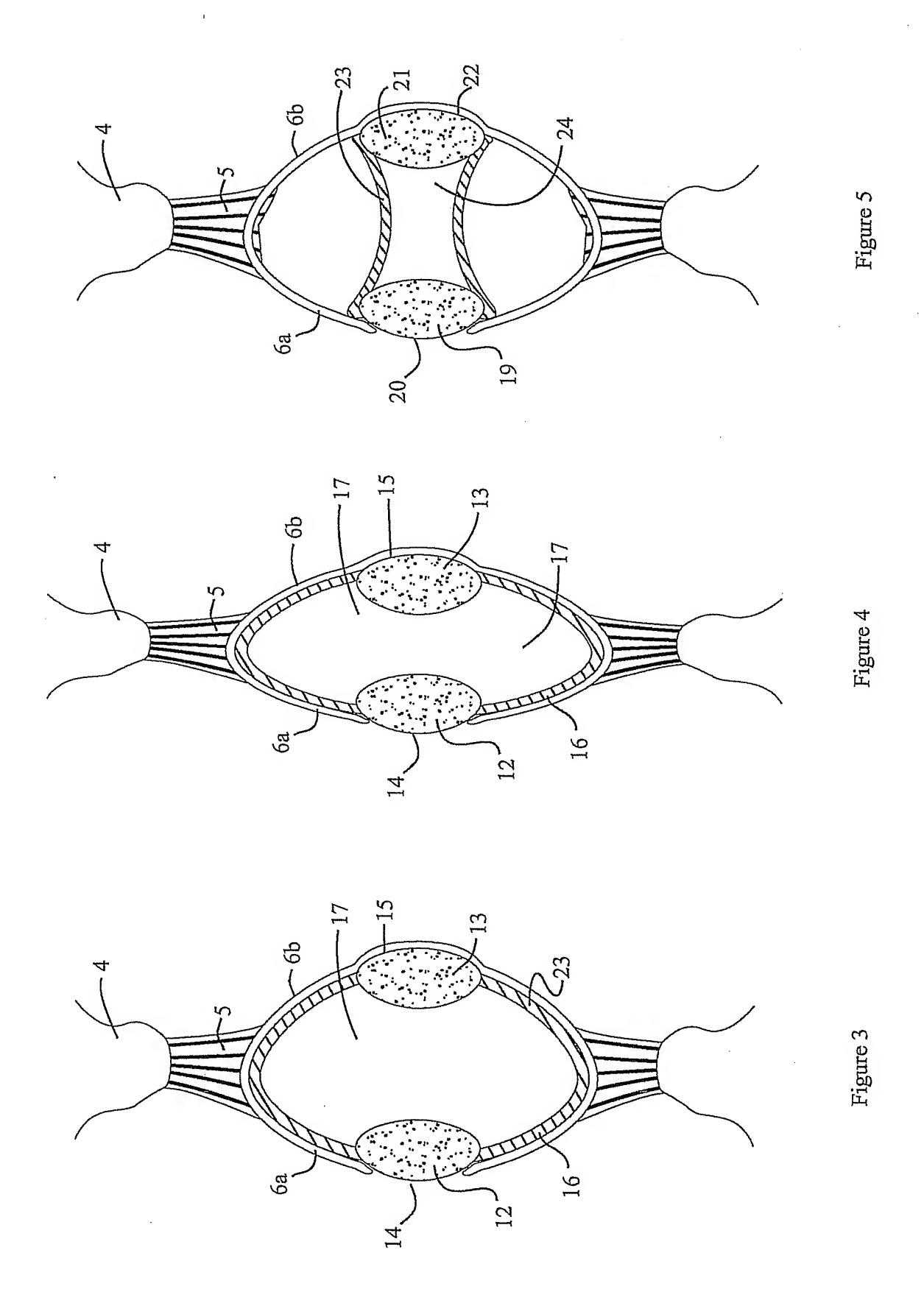
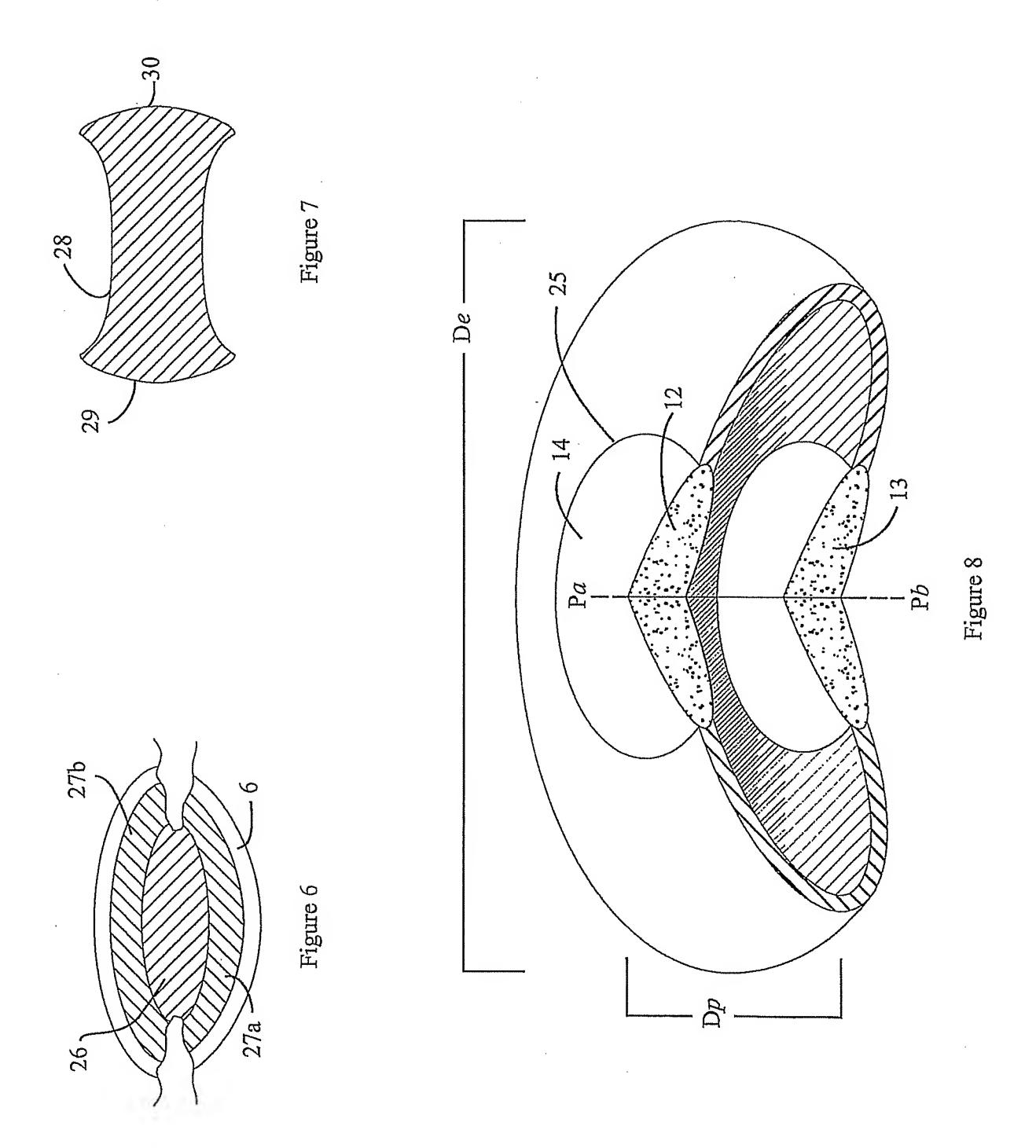


Figure 2







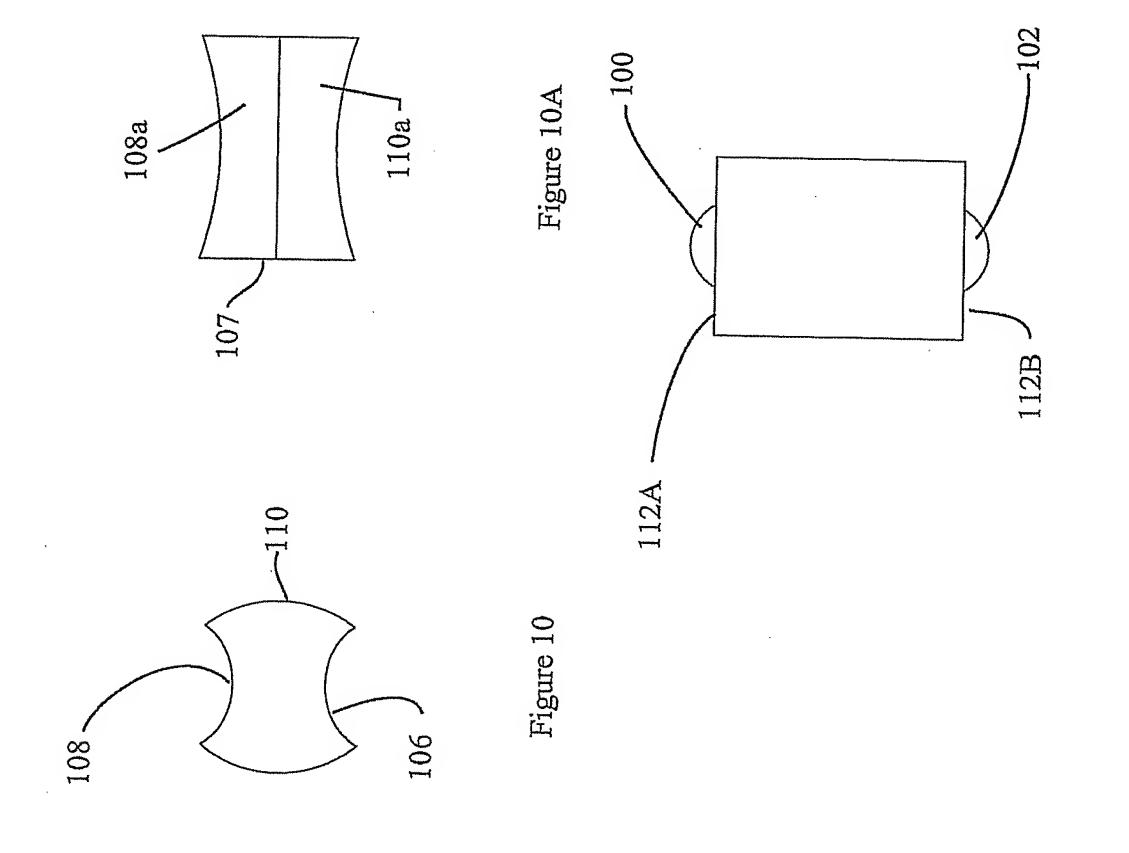


Figure 9A

Figure 91

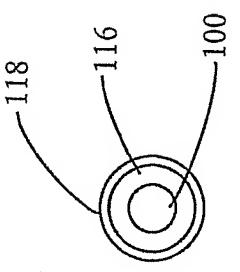


Figure 13B

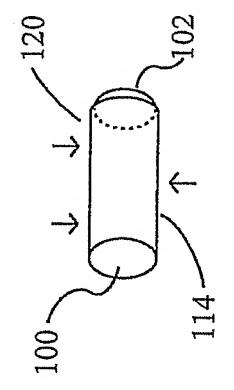


Figure 12

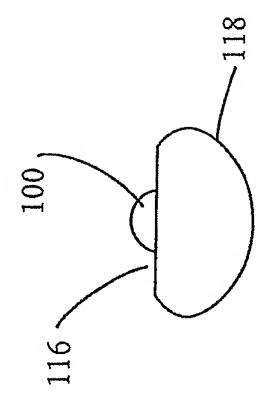
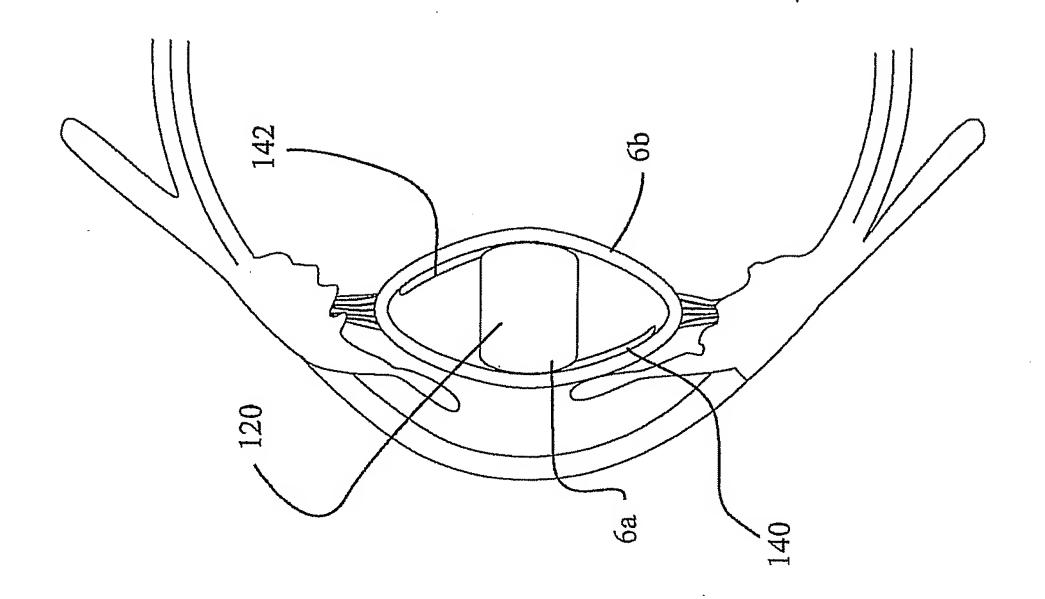


Figure 13A



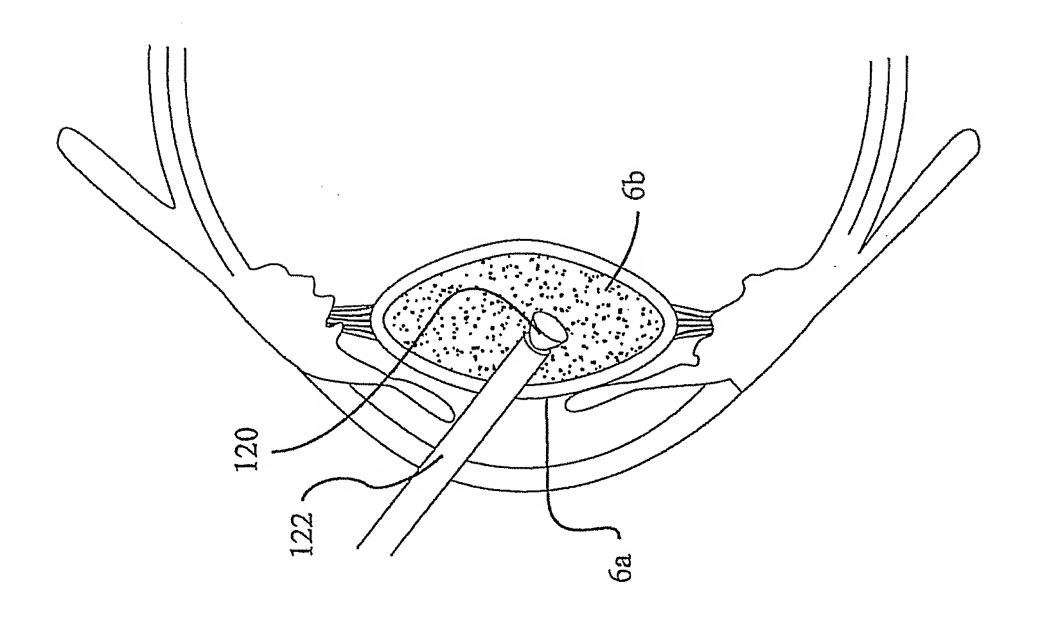
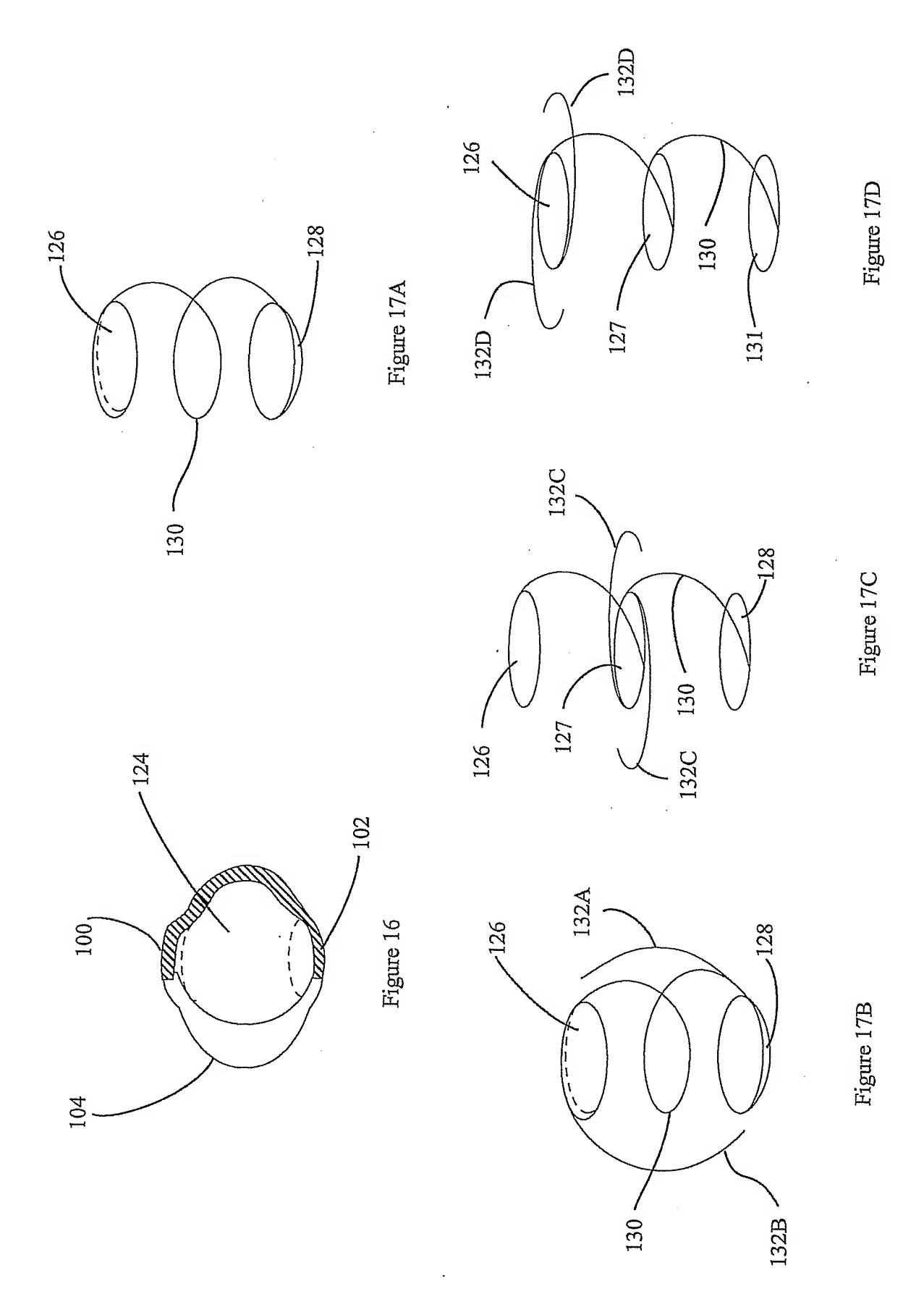


Figure 14



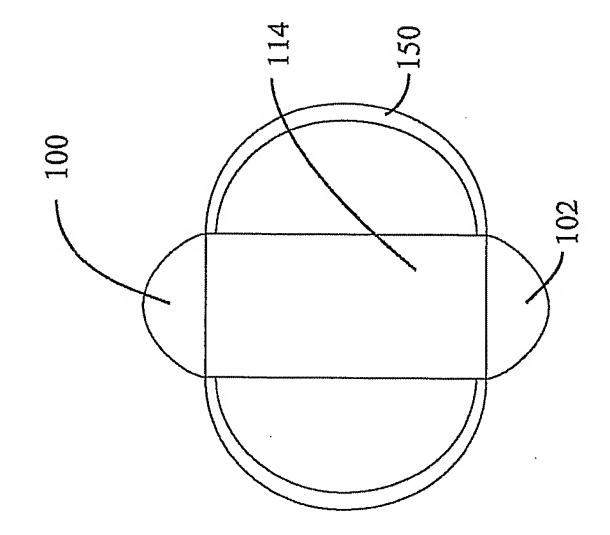


figure 18B

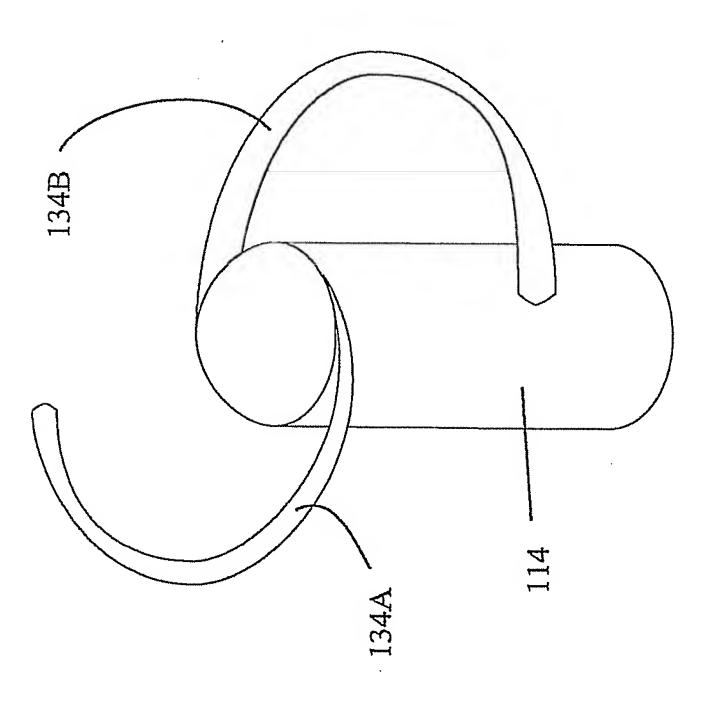


Figure 18A

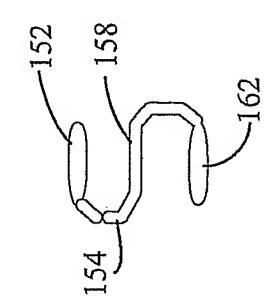


Figure 19C

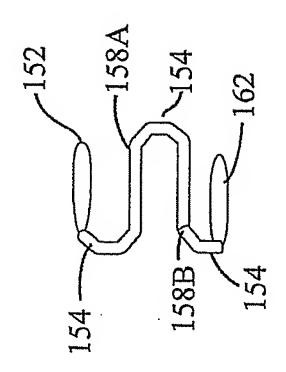
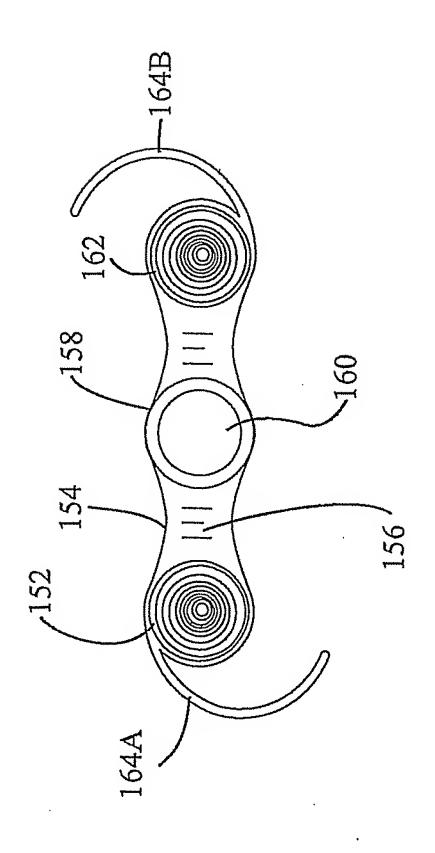
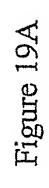
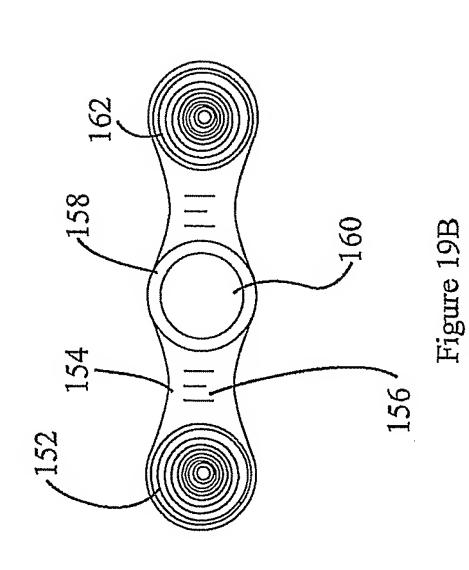


Figure 19D







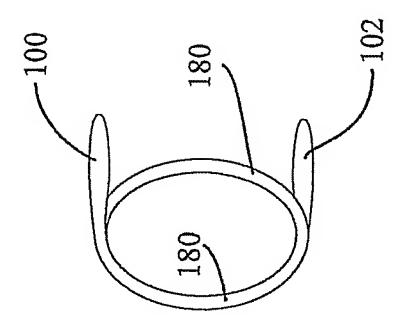


Figure 20C

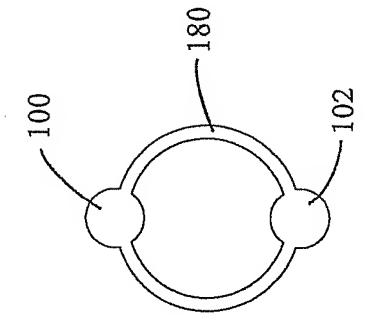
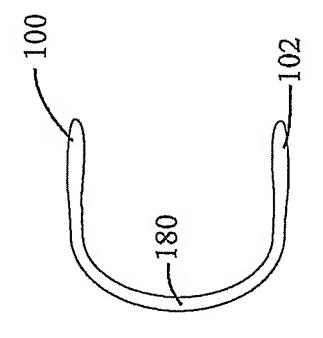
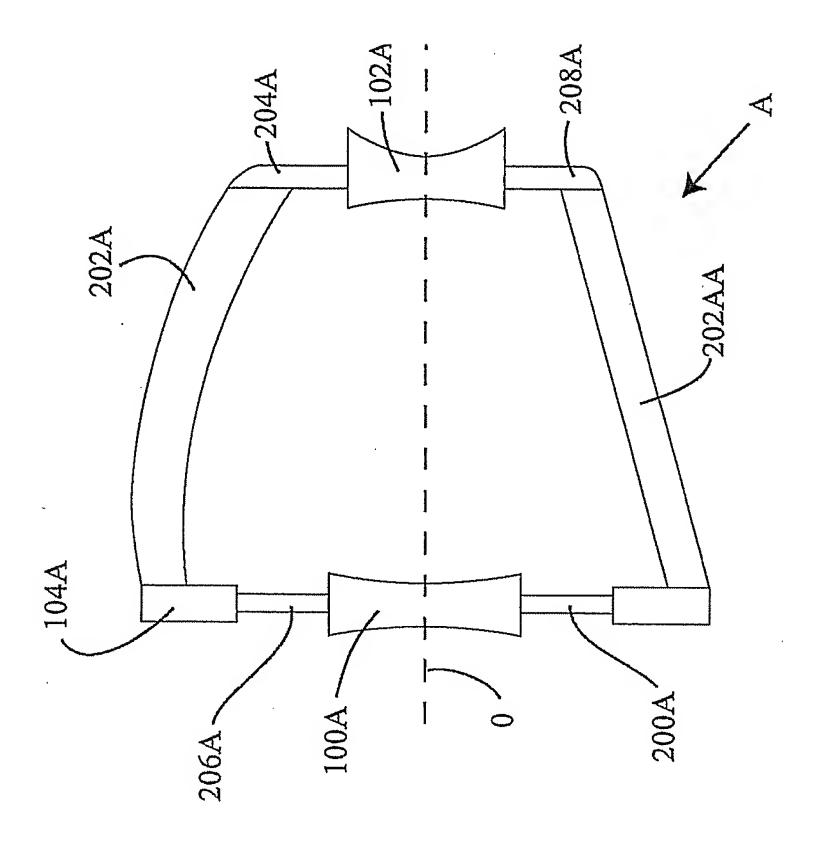


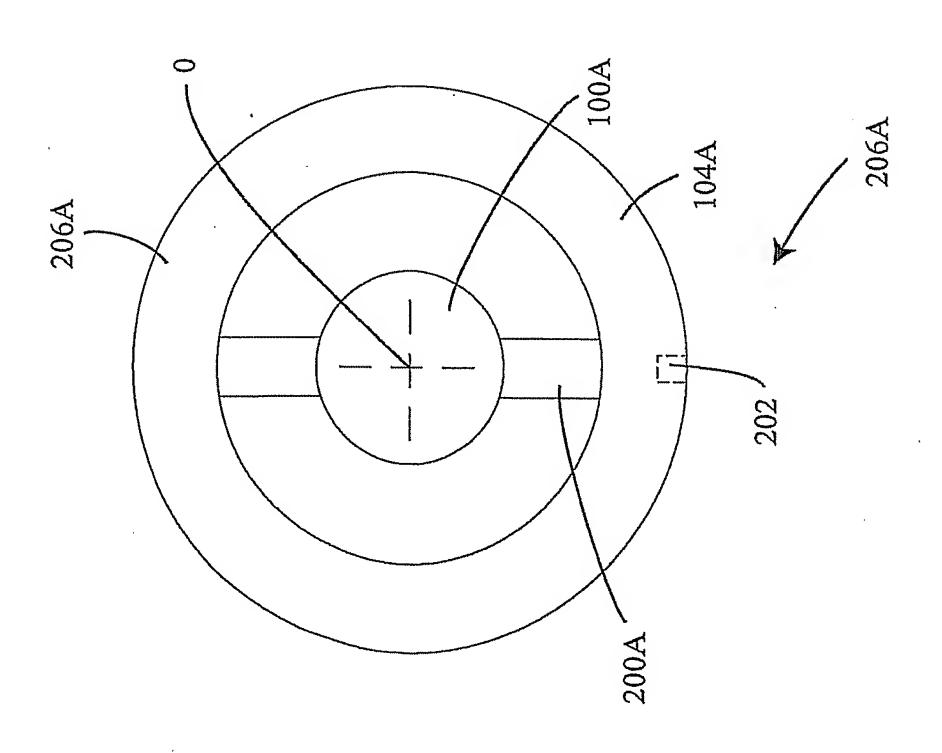
Figure 20A



'igure 20E







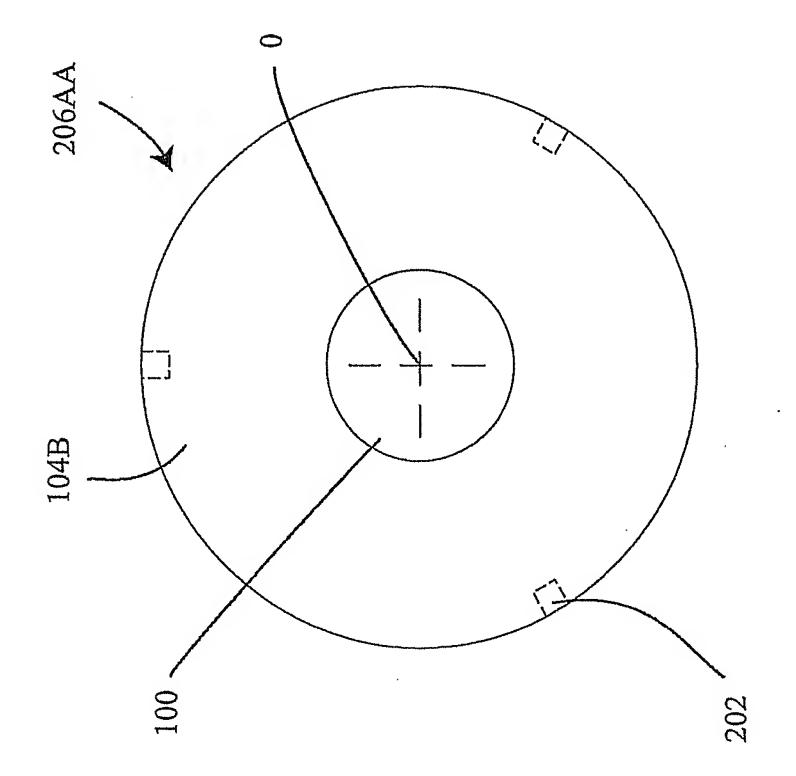


Figure 24

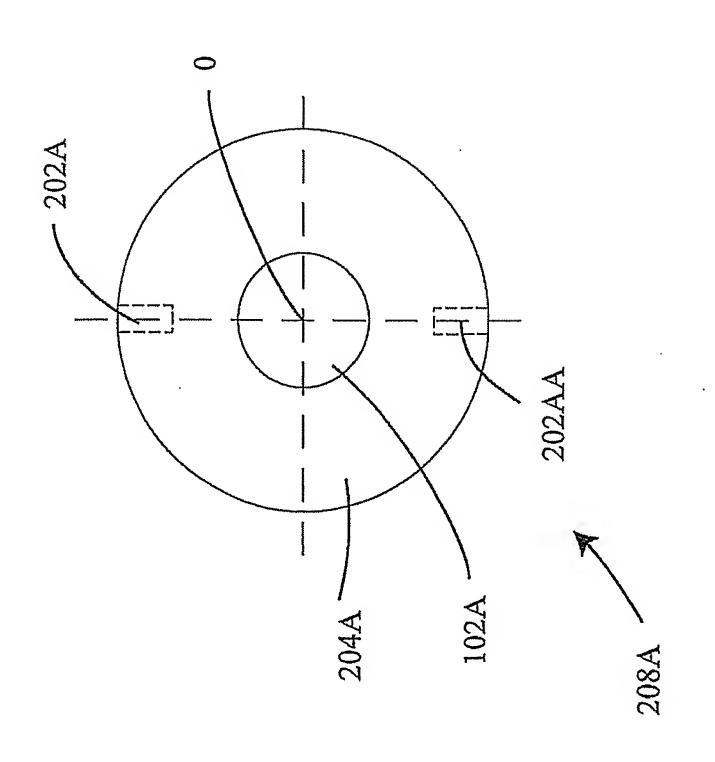


Figure 23

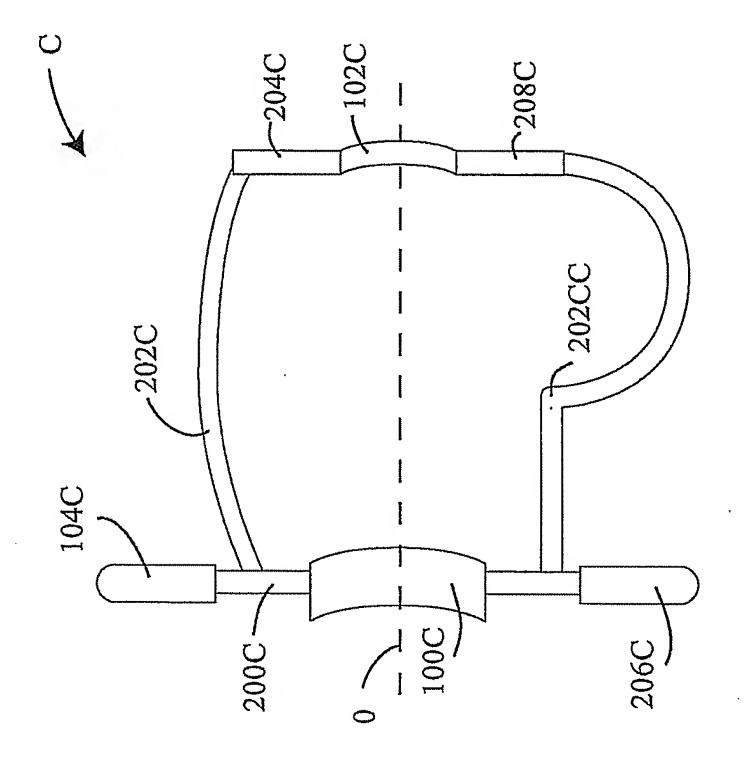


Figure 26

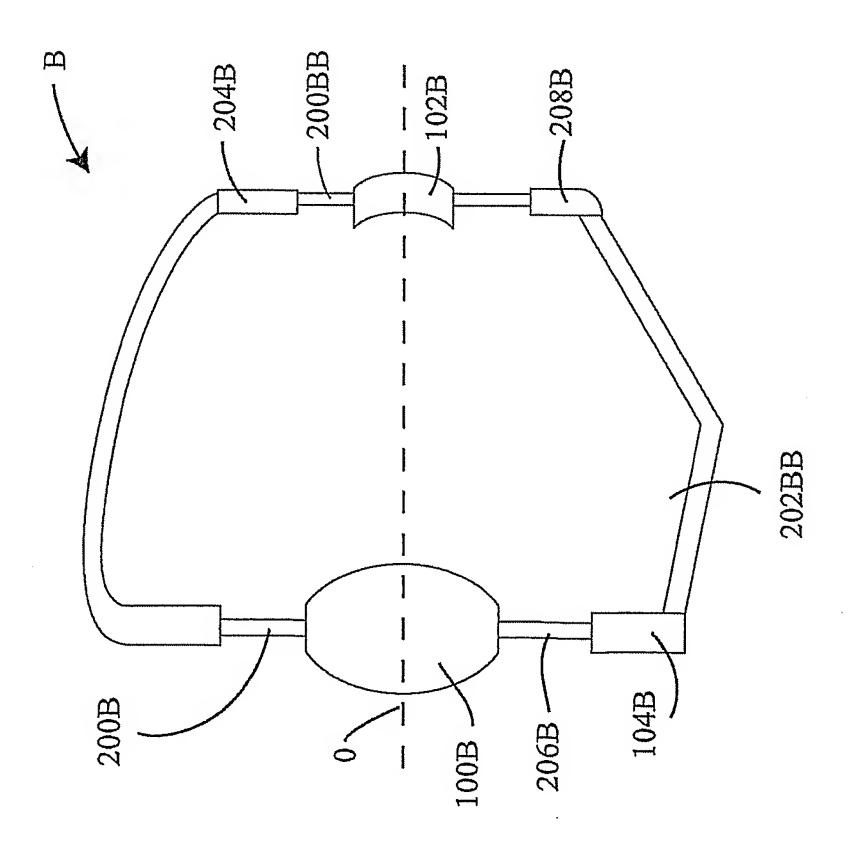


Figure 25

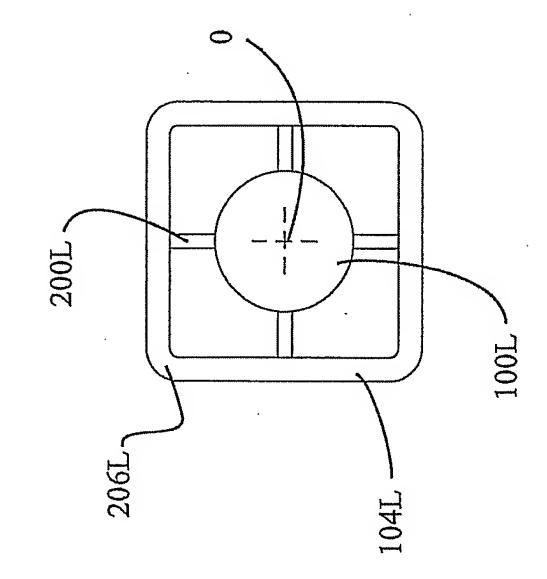


Figure 28

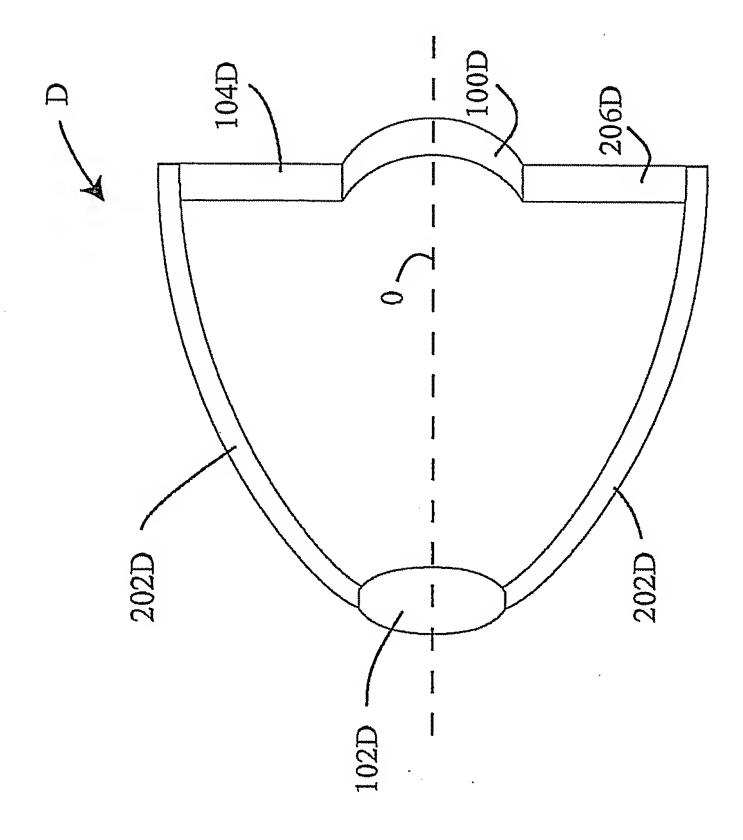


Figure 27

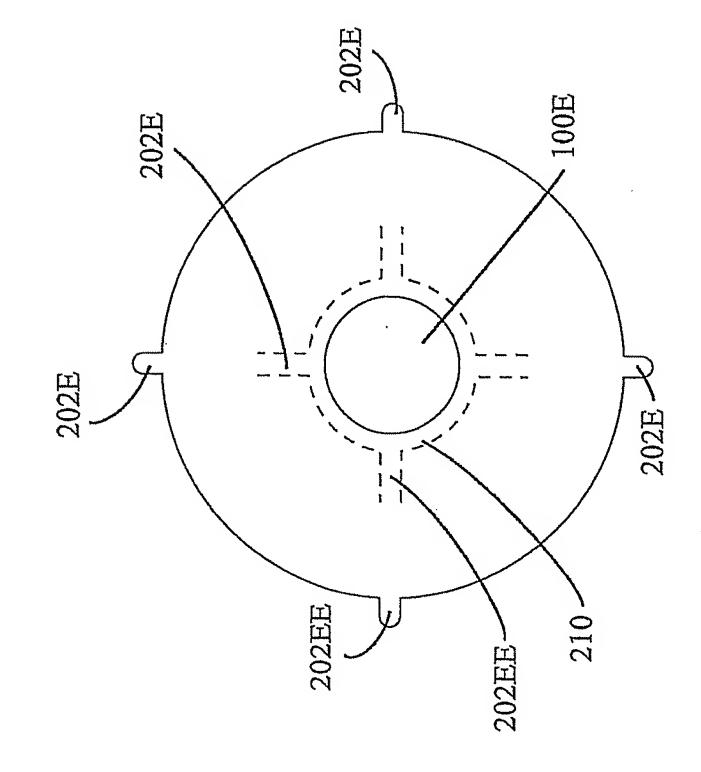


Figure 29a

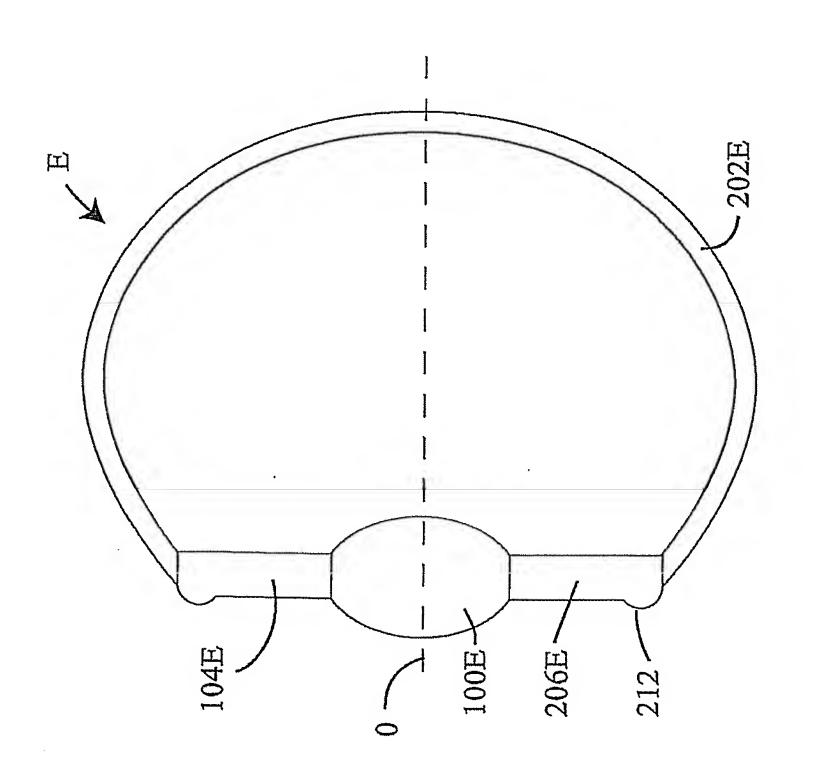


Figure 29

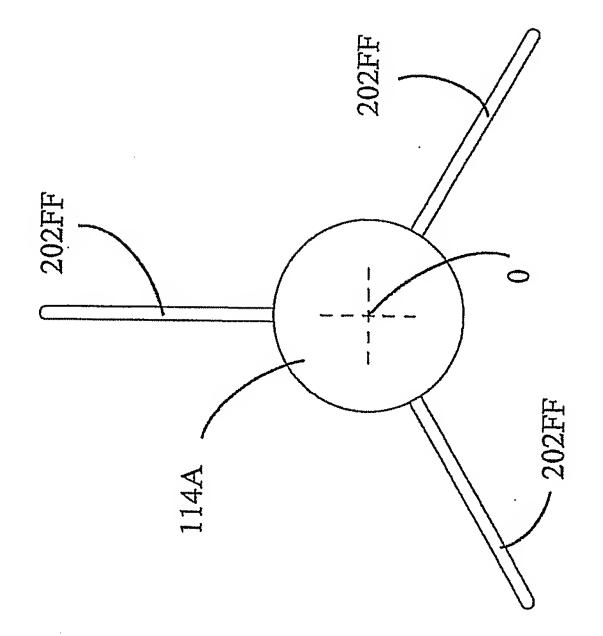


Figure 31

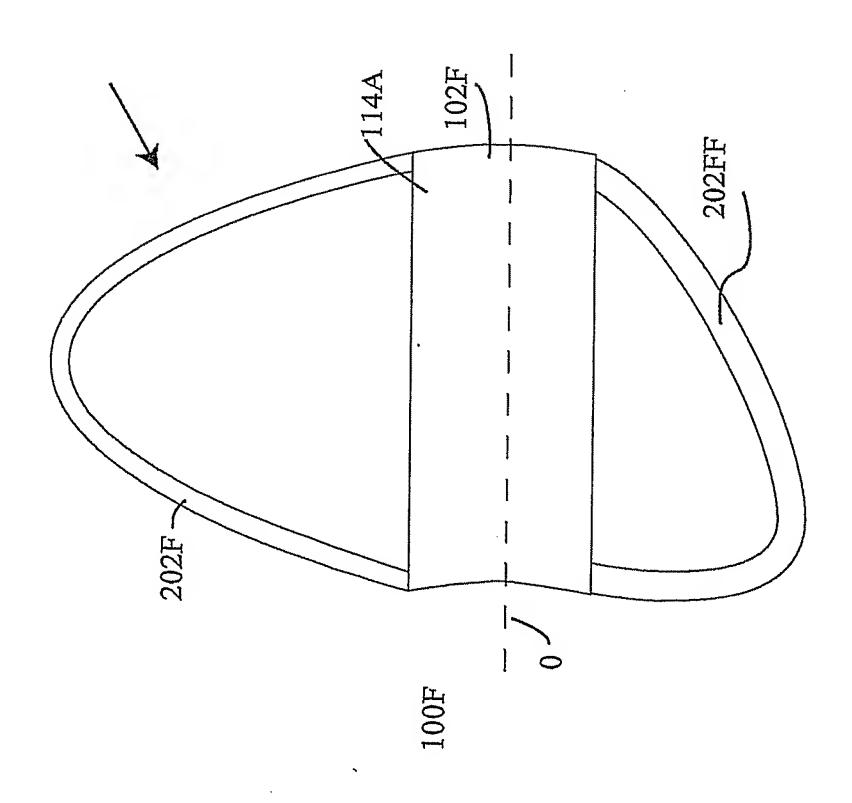


Figure 30

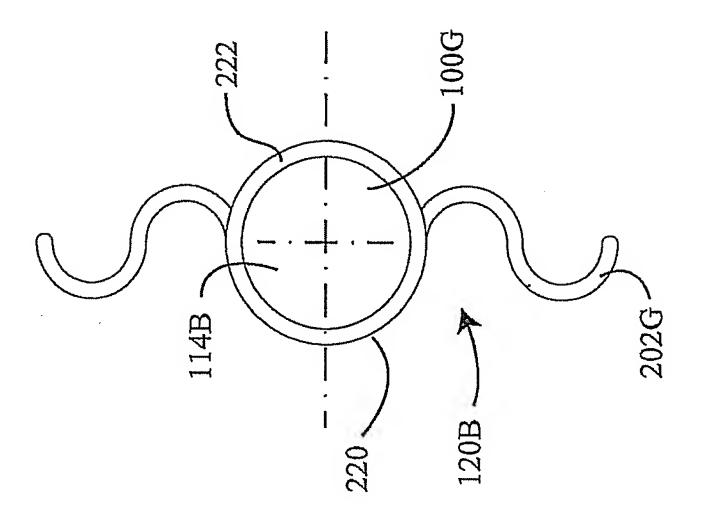


Figure 33

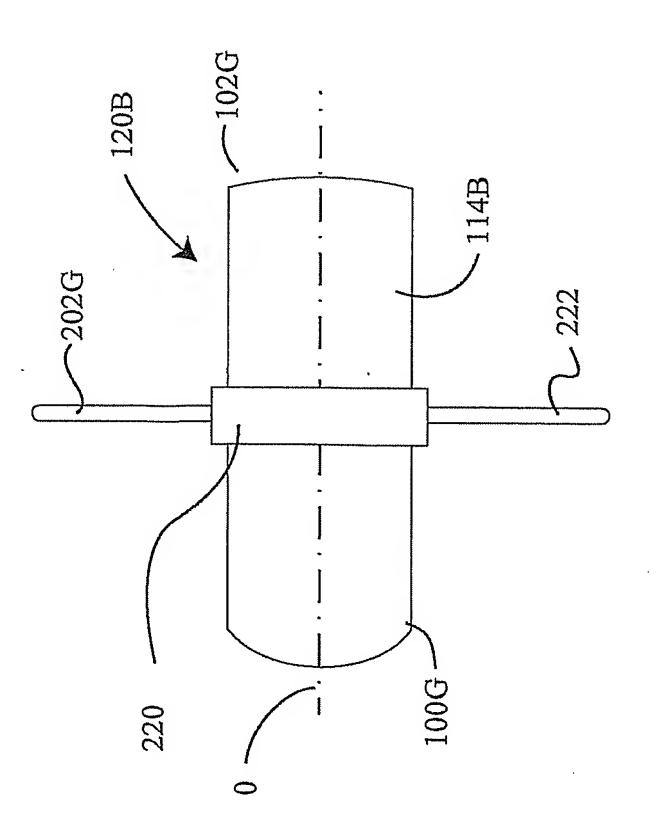
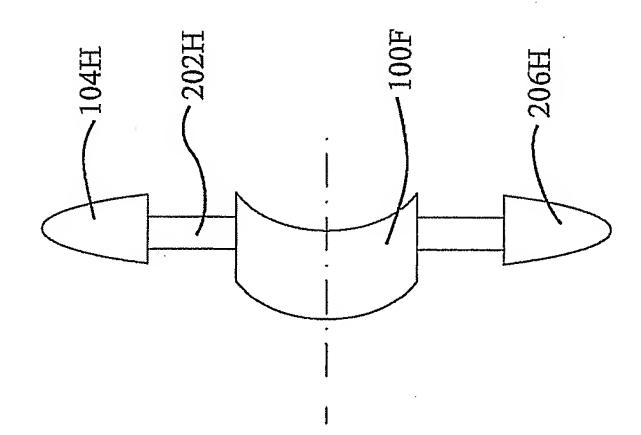


Figure 3.





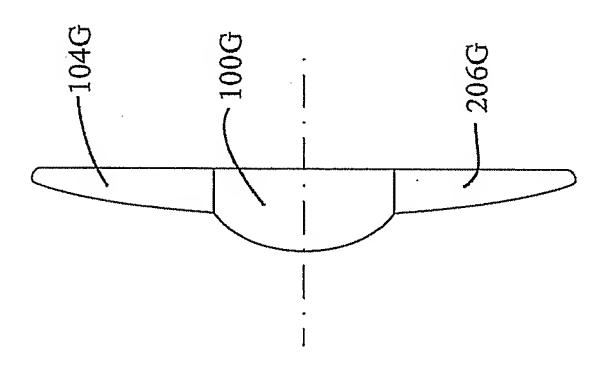


Figure 35

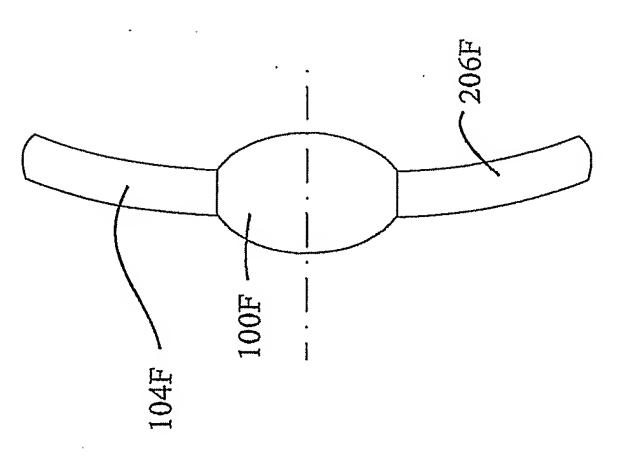


Figure 34

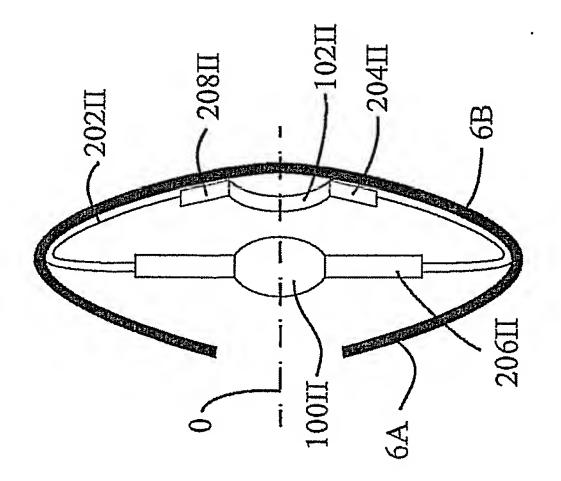


Figure 38

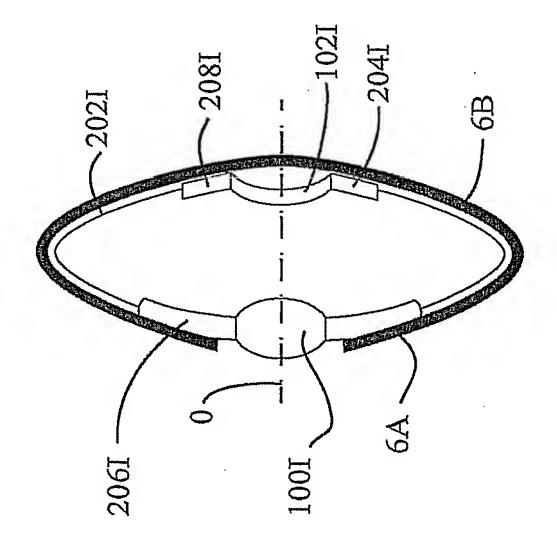
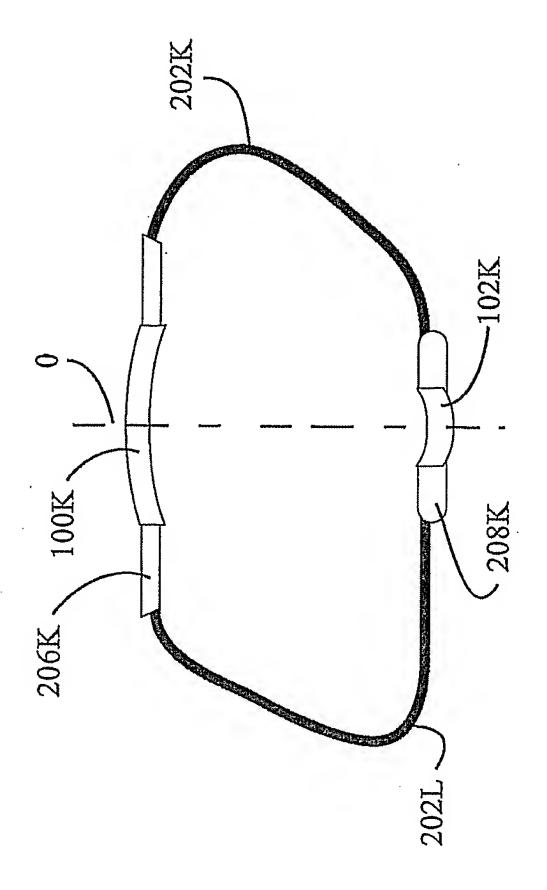
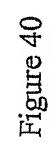


Figure 37





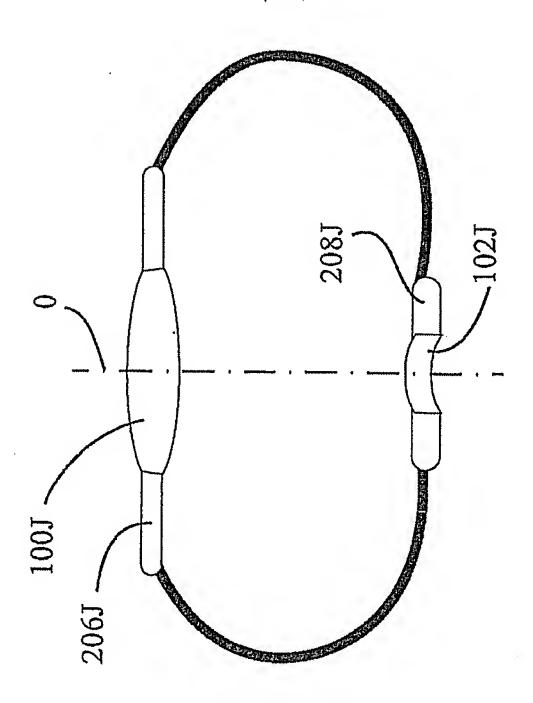


Figure 39

PCT/US 03/19705

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61F2/16 G09B23/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61F G09B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

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X Funt	her documents are listed in the continuation of box C.	γ Patent family members are listed	in annex.
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Date of mailing of the international search report

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9 October 2003

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